UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

KATHRYN M. NELSON, et al.,

Plaintiffs,

v. Case No. 12-C-472

JOHNSON & JOHNSON and
ETHICON INC.,

Defendants.

DECISION AND ORDER

Plaintiff Kathryn Nelson alleges that she was injured as a result of the implantation of a Prolift device that is made by Defendants Johnson & Johnson, a New Jersey corporation, and Ethicon Inc., a New Jersey corporation and subsidiary of Johnson & Johnson. The case was conditionally remanded back to this court from the Southern District of West Virginia on April 26, 2019. When the case was remanded, there were a number of pending motions. On July 15, 2019, the court entered an order granting-in-part and denying-in-part Ethicon's motion for partial summary judgment. Dkt. No. 35. At a telephone conference held on July 24, 2019, the parties advised the court that the remaining pending motions—Nelson's motion to exclude certain opinions of Dr. Scott Serels, Ethicon's motion to exclude the supplemental expert report and opinions of Dr. Dionysios Veronikis, and Nelson's motion to strike Ethicon's non-retained experts—were ready for consideration. The parties had originally asked the court not to decide the motions until the parties determined if the additional medical treatment Nelson had received since the motions were fully briefed warranted any modification or supplementation to the motions. For the following reasons,

Nelson's motion to exclude certain opinions will be denied, Ethicon's motion to exclude the supplemental report will be denied, and Nelson's motion to strike will be granted.

BACKGROUND

On May 14, 2009, Nelson underwent a total vaginal hysterectomy and an anterior and posterior colporrhaphy utilizing the total Prolift graft that was performed by Dr. Thomas Reinardy. In May of 2010, Nelson noticed that she had a severely foreshortened vagina and returned to Dr. Reinardy who diagnosed her with, among other things, a foreshortened vagina. Over the course of the next eighteen months, Nelson underwent multiple operative procedures to deal with the various complications she was experiencing and for partial mesh excision of the Prolift.

LEGAL ANALYSIS

A. Nelson's Motion to Exclude Certain Opinions of Dr. Scott Serels

Nelson seeks to exclude the following three opinions of Dr. Scott Serels because she contends that the testimony fails to meet Rule 702's reliability criteria for expert testimony:

1) That the posterior portion of the Prolift mesh was implanted by Dr. Reinardy, the implanting surgeon, in a manner that caused twisting and bunching of the mesh near the apex of the vagina;

2) That placement of mesh in such a position was a cause of Ms. Nelson's foreshortened vagina; and

3) That this placement was "improper."

Pl.'s Br., Dkt. No. 15 at 2.

Under Rule 702, expert testimony is admissible if "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue," "the testimony is based on sufficient facts or data," "the testimony is the product of

reliable principles and methods," and "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. "Under the *Daubert* framework, the district court is tasked with determining whether a given expert is qualified to testify in the case in question and whether his testimony is scientifically reliable." *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592–93 (1993)). "The non-exclusive list of *Daubert* reliability factors for scientific evidence includes whether or not the theory or technique has been (1) tested, (2) subjected to peer review and publication, (3) analyzed for known or potential error rate, and/or is (4) generally accepted within the specific scientific field." *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 810 (7th Cir. 2012) (citing *Daubert*, 509 U.S. at 593–94). "The court should also consider the proposed expert's full range of experience and training in the subject area, as well as the methodology used to arrive at a particular conclusion." *Gayton*, 593 F.3d at 616 (citing *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000)). The district court has "wide latitude in performing its gatekeeping function and determining both how to measure the reliability of expert testimony and whether the testimony itself is reliable." *Bielskis v. Louisville Ladder, Inc.*, 663 F.3d 887, 894 (7th Cir. 2011).

In his expert report, Dr. Serels opined that the symptoms Nelson has experienced since the implantation of the Prolift were not the result of defects in the mesh implants, but "were largely caused by the improper placement of the Prolift mesh at implant and complications." Dkt. No. 19-1 at 22–23. In reaching this conclusion, Dr. Serels relied on notes from Dr. Reinardy, the implanting surgeon, that stated "I am kind of hoping that this is not in there a little too snuggly as she does seem to have a shortened vagina right now." *Id.* at 22. Dr. Serels also relied on Dr. Rienardy's notes indicating bunching of the mesh at a follow-up visit with Nelson, and stated that bunching

"only results from surgical placement." *Id.* at 22. Dr. Serels pointed to Dr. Reinardy's testimony at deposition that "it was possible that the mesh was deployed at implant in a twisted position" as support for his opinion. *Id.*

Dr. Serels' opinion that Nelson's symptoms are the result of improper placement of the Prolift mesh is based on reliable evidence, and thus is admissible under Rule 702. In his deposition, Dr. Serels testified that, in his experience, shortening of the vaginal canal "correlates with the material maybe being placed not quite at the apex and it creates a neo-apex in an area of the vaginal cuff that's in a location that's closer to the introitus than you'd like it to be." Serels Dep. 114:10–14, Dkt. No. 14-1 at 69. Although he could not cite a study or treatise to support his opinion, *id.* at 124:24–125:3, Dkt. No. 14-1 at 71, Dr. Serels testified that he reached his decision based on his "experience with doing the procedure, experience with giving lectures, teaching courses, colleagues, conferences, [and] knowledge from the medical community." *Id.* at 125:11–14. Dr. Serels stated that he has revised a lot of procedures that were the result of improper placement, although only roughly 20 of those were related to Prolift devices and only a subset of those were for total Prolifts. *Id.* at 125:15–126:15, Dkt. No. 14-1 at 71–72. When asked "how many times have you gone in and seen the posterior arms placed inappropriately, in your mind, and the vaginal vault shortened as result," Dr. Serels answered:

> A: Well, I think the way to look at it is if I went in because of a foreshortened vaginal vault, the majority of those situations have been just improper placement of the arms.
>
> Q: So you think the only way that the vaginal vault can be shortened is if the arms are placed improperly?
>
> A: To that - - I mean, to that dramatic of an extent.

Id. at 126:21–127:5, Dkt. No. 14-1 at 72. Dr. Serels also provided an explanation as to how an improper placement of the Prolift can result in a foreshortening of the vaginal vault:

> In doing the procedure - - the posterior portion of the procedure, you make an incision over the posterior vaginal wall and you dissect to your sacrospinous ligaments. And then you make two small incisions on either side of the anus. And the idea is to take this trocar from the incisions on the skin on the other side of the anus and pass it and catch it on your finger in that vaginal incision in the posterior wall near the rectum and bring it out through that sacrospinous ligament. So when you're, to your point, blindly catching the tip of that needle, if you don't get it all the way up to that sacrospinous ligament or you don't bring it through the sacrospinous ligament, so either your short and soft tissue or the soft tissue just tears as it's healing, you're going to end up with a vaginal apex that's not going to be where you want it at that 9 centimeters.

Id. at 142:11–143:5, Dkt. No. 14-1 at 76.

Based on this testimony, Dr. Serels' opinion that the foreshortening experienced by Nelson may be caused by improper placement of the Prolift is supported as he has explained how his experiences support his conclusion. *See* Fed. R. Evid. 702 Advisory Committee's Note to 2000 Amendment ("If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts."); *see also Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 761–62 (7th Cir. 2010) (opinions based on what expert had seen and experienced during his time in the field were admissible). Although Nelson asserts that Dr. Serels' opinions should be excluded because he has failed to show that his theory based on his experience "had any general acceptance in the scientific or medical community or how his giving lectures or teaching courses could establish any scientific reliability of his opinion in the absence of testing or peer-reviewed publications," Pl.'s Br., Dkt. No. 15 at 11, "[e]xperts of all kinds tie observations to conclusions through the use of what Judge Learned Hand called 'general

truths derived from . . . specialized experience.'" *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 148 (1999) (citing Learned Hand, *Historical Practical Considerations Regarding Expert Testimony*, 15 HARV. L. REV. 40, 54 (1901)). Here, Dr. Serels' experience has been observing shortened vaginal vaults as a result of the arms of an implanted mesh improperly being placed. Based on these experiences, Dr. Serels concluded that the arms of the Prolift must be improperly placed from his observations that Nelson has a shortened vaginal vault.

Nelson's challenges to Dr. Serels' testimony go more to weight, rather than admissibility. Nelson asserts that there is no evidence to support Dr. Serels' opinion that the Prolift mesh was implanted in a twisted or bunched manner by Dr. Reinardy. In support of this assertion, Nelson cites Dr. Serels' admission that he cannot provide any physical evidence of bunching of the mesh at the apex, Serels Dep. 116:2–5, Dkt. No. 14-1 at 69, or see any evidence that any physician actually observed any bunching. *Id.* at 121:9–18, Dkt. No. 14-1 at 70. But Dr. Serels' opinion in his report is not that bunching or twisting of the mesh was the sole cause of the improper placement of the Prolift, as Nelson contends. Rather, Dr. Serels' opinion is that, given the shortening of Nelson's vaginal vault, the Prolift was improperly placed by Dr. Reinardy as it has been his experience that, when he has observed this condition, it has been the result of improper placement. Dr. Serels cites a note by Dr. Reinardy that mentions bunching of the mesh as evidence in support of his opinion that the Prolift was improperly implanted, not as the sole root cause of Nelson's vaginal shortening. The "soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact." *Smith*, 215 F.3d at 718. This is the sort of issue that can be addressed through "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the

burden of proof." *Daubert*, 509 U.S. at 596. Consequently, Nelson's motion to exclude certain opinions of Dr. Serels will be denied.

B. Ethicon's Motion to Exclude the Supplemental Expert Report and Opinions of Dr. Dionysios Veronikis

Ethicon seeks to exclude the supplemental expert report and opinions of Dr. Dionysios Veronikis, asserting that the opinions expressed in the supplemental report are not proper rebuttal opinions. In his initial expert report, which was timely disclosed to Ethicon on May 3, 2016, Dr. Veronikis opined that the implantation of the Prolift device caused: (1) significant vaginal foreshortening and atresia, vaginal tissue scarring, erosion, and chronic vaginal pain; (2) severe and chronic pelvic pain consistent with pelvic floor myalgia; and (3) severe compromise of Nelson's quality of life based on the mesh complications outlined in (1) and (2) above. *See* Dkt. No. 20-1 at 15–18. Dr. Veronikis also opined that he used a differential diagnosis and ruled out other potential causes for the injuries he identified. *Id.* at 17–18.

On June 3, 2016, Ethicon timely disclosed the expert report of Dr. Scott Serels. In addition to the opinions summarized earlier, Dr. Serels opined that the "introduction of the laparascopy also created an opportunity for future complications such as abdominal adhesions." Dkt. No. 19-1 at 23.

On June 16, 2016, Nelson timely disclosed the rebuttal report of Dr. Veronikis in which he opined that (1) there was no evidence that the Prolift mesh was implanted improperly; (2) Prolift can become bunched even when implanted in accordance with the manufacturer's instructions; (3) contracture and shrinkage of the Prolift mesh can occur even in the absence of twisting, bunching and/or folding of the mesh; and (4) neither the laparoscopy nor the DermMatrix Graft implant contributed to Nelson's chronic vaginal and pelvic pain. *See* Dkt. No. 19-1 at 2–5. Specifically,

regarding Dr. Serels' opinion that Nelson's complications are largely caused by the improper placement of the Mesh Prolift, Dr. Veronikis opined:

> Dr. Reinardy's statements were made at a time prior to his revision surgery, when physical examination would not allow for a proper determination on exact position of the Prolift mesh. Based on the records associated with Dr. Reinardy's July 22, 2010 revision surgery, when the revision surgery was actually conducted there was no finding in the operative report of any bunching, folding or twisting of the mesh implant. In Dr. Reinardy's deposition, he does not indicate he found any bunching, twisting or folding of the mesh implant during revision surgery. In fact, in his deposition, Dr. Reinardy indicated that, when he made his incision at the apex of the vagina, the mesh implant was not placed in a twisted position. (Reinardy Dep.p.p. 80-81, 152). Finally, none of the physicians involved in Ms. Nelson's subsequent revision surgeries described mesh in a twisted, bunched or folded condition.

Id. at 2. Regarding the laparascopy, Dr. Veronikis opined that, because it "was not done in an area where the likely pain generators for Ms. Nelson are located," it likely was not a contributing factor. *Id.* at 4.

The crux of Ethicon's motion is that, because Dr. Veronikis did not address the laparascopy or the possibility that the Prolift mesh was improperly implanted as causes of Nelson's conditions in his initial report, his rebuttal report constitutes improper supplementation. "The proper function of rebuttal evidence is to contradict, impeach or defuse the impact of evidence offered by an adverse party." *Peals v. Terre Haute Police Dep't*, 535 F.3d 621, 630 (7th Cir. 2008) (quoting *United States v. Grintjes*, 237 F.3d 876, 879 (7th Cir. 2001)). "A rebuttal report 'should be limited to 'contradict[ing] or rebut[ing] evidence on the same subject matter identified by another part.'" *Larson v. Wis. Cent. Ltd.*, No. 10-C-446, 2012 WL 368379, at *4 (E.D. Wis. Feb. 3, 2012) (alterations in original) (quoting *Butler v. Sears Roebuck & Co.*, No. 06 C 7023, 2010 WL 2697601, at *1 (N.D. Ill. July 7, 2010)). "Testimony offered only as additional support to an argument made in a case in chief, if not offered to contradict, impeach or defuse the impact of the evidence offered

by an adverse party, is improper on rebuttal." *Peals*, 535 F.3d at 630 (quotation marks omitted). If parts of an expert's testimony constitute "improper bolstering while other parts fairly respond to the conclusions of the opposing party's experts, the appropriate course is to limit the proposed rebuttal expert's testimony rather than striking it altogether." *Cage v. City of Chicago*, No. 09 C 3078, 2012 WL 5557410, at *2 (N.D. Ill. Nov. 14, 2012) (collecting cases).

Dr. Veronikis' rebuttal report will not be excluded. The opinions Dr. Veronikis expressed within the report directly address the opinions presented by Dr. Serels and set forth why, in his opinion, Dr. Serels' conclusions are not supported by the record. Ethicon asserts that, because Dr. Veronikis did not rule out the laparascopy or improper placement of the Prolift as potential causes in his differential analysis, Dr. Veronikis' rebuttal report is less of a rebuttal and more of an attempt to correct these oversights in his initial report. But Dr. Veronikis' rebuttal of these potential causes is essentially that there was no reason to think that they could have caused the injuries, and thus no need to rule them out. Regarding the laparascopy, Dr. Veronikis stated that it "was not done in an area where the likely pain generators for Ms. Nelson are located." Dkt. No. 19-1 at 4. Addressing improper placement, Dr. Veronikis explained that there was no evidence of misplacement when the revision surgery was conducted and that none of the physicians involved in Nelson's revision surgeries described the mesh as twisted, bunched, or folded. As the rebuttal report directly addressed the opinion and conclusions of Dr. Serels, Ethicon's motion to exclude the rebuttal report will be denied.

C. Nelson's Motion to Strike Ethicon's Non-Retained Experts

Nelson seeks to strike the non-retained experts listed in Ethicon's expert disclosure because she argues the parties are limited in the number of experts by the pretrial order that was issued when this case was a part of the MDL. On November 20, 2015, Judge Goodwin of the Southern District of West Virginia entered a scheduling order when this case was a part of the MDL that limited parties "to no more than five (5) experts per case (exclusive of treating physicians)." Dkt. No. 8-13 at 3. On June 16, 2016, the scheduling order was amended per the parties' stipulation "based on the plaintiff's designation of separate specific causation expert witnesses with regard to the plaintiff's physical, psychological and vocational injuries/damages." Dkt. No. 8-14 at 1. Ethicon was also allowed an additional expert should it choose "separate specific causation expert witnesses" to address those issues. *Id.* On June 3, 2016, in addition to identifying four expert witnesses who may be called to testify at trial, Ethicon identified thirteen consultants and former Ethicon employees as non-retained experts. Dkt. No. 25-1 at 3–84.

As an initial matter, Ethicon asserts that Nelson's motion, which was filed on March 7, 2017, is untimely because it was filed after the July 1, 2016 discovery deadline and the July 21, 2016 *Daubert* motion deadline. As Nelson points out however, the November 20, 2015 scheduling order did not impose a deadline for motions *in limine*. Consequently, the court finds that Nelson's motion is timely.

Judge Goodwin addressed this issue in another case that was part of the Ethicon MDL. In *Lankston v. Ethicon, Inc., et al.*, No. 2:12-cv-00755 (S.D. W. Va.), which was subject to the same November 20, 2015 scheduling order, the defendants designated four retained experts and seven non-retained experts that would "testify primarily as lay witnesses" and "will only testify as experts

to the extent they may be called upon to answer some questions using knowledge accrued through the course of their employment or training." *Lankston*, Dkt. No. 148 at 1. The plaintiff filed a motion to strike the non-retained experts because the total number of experts exceeded the limit of five set forth in the scheduling order. The court granted the motion, stating the scheduling order limited each side to no more than five experts and that the additional experts "must be excluded" because "[t]he defendants have designated more than the five allotted experts in violation of this court's express limitation." *Id.* The court clarified though that, to the extent the defendants sought to elicit lay testimony from the non-retained experts, "that testimony is, of course, admissible subject to the evidentiary rulings of the court at trial." *Id.* at 2.

Given the intent of the expert witness limit as explained in *Lankston*, Nelson's motion will be granted. As Ethicon has only identified four expert witnesses, it may choose one of the non-retained experts to include in its expert witness list. In addition, similar to *Lankston*, to the extent Ethicon intends to elicit lay testimony from the non-retained experts, such testimony is admissible subject to evidentiary rulings at trial.

CONCLUSION

For the foregoing reasons, Nelson's motion to exclude certain opinions of Dr. Serels (Dkt. No. 14) is **DENIED**, Ethicon's motion to exclude the supplemental expert report and opinions of Dr. Dionysios Veronikis (Dkt. No. 18) is **DENIED**, and Nelson's motion to strike Ethicon's non-retained experts (Dkt. No. 25) is **GRANTED**.

SO ORDERED this 7th day of October, 2019.

s/ William C. Griesbach
William C. Griesbach, Chief Judge
United States District Court